52.(New) A method for treating tumors of epithelial origin in patients to retard the development of these tumors comprising administering to said patient a composition containing a compound selected from the group consisting of 9-*cis* retinoic acid and its pharmaceutically acceptable formulations, said compound being administered in an amount effective to retard the development of said tumors.

53.(New) A composition in unit dosage form for oral administration comprising as an active ingredient a compound selected from the group consisting of 9-*cis* retinoic acid and its pharmaceutically acceptable formulations and a pharmaceutically acceptable carrier suitable for oral administration.

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**Remarks**

This amendment is submitted to present new claims ancillary to the purpose of provoking an interference with U.S. 5,428,071, a copy of which is attached hereto as Exhibit A. The patent in question, assigned to Hoffmann-La Roche Inc. of Nutley, New Jersey and hereinafter referred to as the "Roche Patent," issued on Serial No. 08/201,493, filed February 24, 1994, which was a continuation of Serial No. 07/833,741, filed January 22, 1992, and now abandoned. The claims of the Roche Patent relate to a pharmaceutical formulation of 9-cis-retinoic acid and the use of 9-cis-retinoic acid to treat epithelial cancers and premalignancies.

The present application was filed on June 14, 1994 as a continuation-in-part of Serial No. 07/809,980, filed December 18, 1991. Therefore, Applicants enjoy an earlier effective filing date than the Roche Patent, whose earliest effective filing date is January 22, 1992. The present application discloses and claims, inter alia, 9-cis-retinoic acid and its uses for treating various conditions, including a number of cancers. Accordingly, Applicants are entitled, prima facie, to a patent on claims which find support in their patent application even if the subject matter claimed falls within the scope of claims of the Roche Patent. That prima facie case can only be rebutted in an interference proceeding between the Roche

Patent and the present application on the basis of one or more counts corresponding to at least one claim in the Roche Patent and to at least one patentable claim in the present application.

It is respectfully submitted that the newly proposed claims are patentable, both over the prior art identified by Applicants and over the art identified in the prosecution of the Roche Patent, and because they find support in an application with an earlier effective filing date than the Roche Patent. In that regard, support for the newly added claims are found in the specification of the parent application, which is attached hereto as Exhibit B. More specifically, newly presented claims 51 and 52 find support in the specification of the above-identified application, and in particular at page 11, lines 5 through 30. Further, newly presented claim 53 finds support in the specification of the above-identified application, and in particular at page 24, lines 13 through 19.

With respect to the patentability of the newly proposed claims over the prior art, Applicants submit that this has already in effect been determined by the Patent and Trademark Office. In that regard, there can be no prior art against Applicants that is not also prior art against the Roche Patent, based on the effective filing dates of each, since Applicants' filing date precedes that of the Roche Patent and Roche did not have to avoid any art using the procedure of 37 C.F.R. 1.131, i.e., there was no need to avoid a reference having an effective date less than one year before the effective filing date. Accordingly, in the absence of art not cited against the Roche Patent, which is clearly more relevant to patentability, subject matter in Applicants' case which corresponds to subject matter claimed by the Roche Patent should be considered patentable to Applicants since Roche's claims enjoy a statutory presumption of validity over the prior art.

**Summary**

This application presents one of those unfortunate situations when a patent issues to one applicant when another applicant has an application pending which claims substantially the same subject matter as that patented. Normally an interference proceeding would decide the outcome and only one patent would issue.

In such a proceeding, Applicants would have been Senior Party as a result of their earlier effective filing date. Applicants have, therefore, clearly been prejudiced by the issuance of the Roche Patent without an interference. That prejudice can only be removed by the Examiner promptly determining the allowability of the present claims and initiating procedures to declare an interference. That action is respectfully requested.

Respectfully submitted,

Date: 7/25/95

By: _____

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Attachments